

Institute for Safe Medication Practices
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FOR IMMEDIATE RELEASE
June 6, 2011

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ISMP Warns that Emphasizing Speed in
Community Pharmacy Prescription Dispensing
Can Lead to Errors

Horsham, Pa---The Institute for Safe Medication Practices (ISMP) is sending a strong warning about a safety issue illustrated by a wave of recent national advertising-promoting and rewarding the speed at which community pharmacies dispense prescriptions. The Institute has written to the National Association of Boards of Pharmacy (NABP) to ask for its support in discouraging speed as a primary marketing tool for pharmacy services.

One of the largest pharmacy chains, Rite Aid Corporation, now advertises a "IS-Minute Prescription Guarantee" where up to three new prescriptions will be dispensed within 15 minutes (average of about 5 minutes) or less. If a pharmacy fails to meet the mark, the customer receives a gift card. And other chains as well as independent pharmacies have initiated advertising campaigns that offer similar guarantees to motivate customers.

A 15-minute dispensing claim for up to three prescriptions can jeopardize public health by putting pressure on pharmacists to work as quickly as possible and discouraging them from checking the patient's history and drug profile; looking for possible drug interactions or duplications and other drug use evaluation concerns; calling physicians' offices for clarification; and educating patients about the proper use of prescriptions (as required by federal regulations).

ISMP has received reports from consumers about serious medication errors in community pharmacies where the pharmacist seemed so rushed that work could not be thoroughly checked. Examples of errors due to volume and workplace distractions have been published in the *ISMP Medication Safety Alert! Community/Ambulatory Care Edition* newsletter.

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ISMP believes that prescription guarantees help promote the idea that the dispensing of medications is a 'quick in and quick out process' concerned only with counting tablets. ISMP finds it unacceptable to hold pharmacists to an unrealistic timeframe that can lead to medication errors. Instead, pharmacies should promote the clinical activities they perform and the availability of patient education services.

ISMP applauds the decision by New York State to outlaw the use of "inducements" (e.g., gift cards, coupons) to garner business. We urge other states, through their boards of pharmacy, to follow New York's example.

In addition to writing to NABP, ISMP has featured this issue in the *ISMP Medication Safety Alert!* Acute Care and Ambulatory/Community Care editions as well as ISMP President Michael Cohen's health blog (<http://www.philly.com/phillyfblogs/healthcare/Dont-let-speed-determine-your-choice-of-pharmacy.html>).

For a copy of ISMP's letter to NABP, go to: <http://www.ismp.org/docs/safetyissue.pdf>

About ISMP: The Institute for Safe Medication Practices (ISMP) is an independent, nonprofit charitable organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 35 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. ISMP is a federally certified patient safety organization (PSO), providing healthcare practitioners and organizations with the highest level of legal protection and confidentiality for patient safety data and error reports they submit to the Institute. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.

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Acute Care

ISMP Medication Safety Alert

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EVIDENCE-BASED MEDICINE DOESN'T PRECLUDE COMMON SENSE

From the January 29, 2004

If you went skydiving, would you first ask for scientific evidence from a randomized trial that a properly functioning parachute prevents injury before you'd consider using one during your freefall? Hardly. In fact, no such study exists. (1) Of course, some people without a parachute have survived a freefall from extraordinary heights without injury, and others have sustained injuries even when using a parachute. But it's clear that you'd use a parachute when skydiving, even without a single randomized trial proving its effectiveness. Yet, when it comes to medicine, clinicians may be reluctant to employ any interventions absent rigorous scientific evidence regarding its efficacy.

Evidence-based medicine. This need for rigorous scientific evidence evolved from a history of medicine that's littered with practices that were later abandoned after scientific scrutiny showed that they were ineffective, perhaps even harmful. (2) As such, we are among the many who would agree with evidence-based medicine. However, when it comes to patient safety, there are significant obstacles to this approach.

Limited research on patient safety. Error prevention is still a new field that has attracted just a fraction of the funding of all medical research performed today. Thus, you're likely to find rigorous scientific evidence related to clinical interventions, drugs, and devices used to prevent complications from care that are not associated with errors. But many obvious error-reduction strategies are noticeably absent in available research. Conversely, if you applied only evidence-based safety interventions, you could end up with an ineffectual safety program that, perhaps, focuses on safety issues of lesser importance than those that are problematic in your organization.

Feasibility issues. Obvious ethical and recruitment difficulties preclude a randomized trial of parachute effectiveness; similar problems exist for some patient safety interventions. After all, who would allow themselves or their family member to be randomized into a control group—be it freefalling without a parachute or being the recipient of a prescription using an abbreviation like "U" for units, each with anecdotal evidence of causing harm. Moreover, an institutional review board would never approve either study. The incredibly large scope of a study that could prove efficacy might also be a limiting factor. Take the safety practice of requiring a leading zero for doses less than one. (2) Perhaps only 1 in 100 clinicians will misread the dose as a whole number if the leading zero is omitted. Of those, maybe 1 in 5 reach the patient, and 1 in 10 of those errors cause significant harm. It would be incredibly difficult to carry out a controlled study of sufficient size to prove that patient harm is reduced when using leading zeros. More to the point, is such a large and costly study needed if experience tells us that leading zeros reduce the risk of errors, some of which have caused significant patient harm?

A more balanced approach. In the end, a traditional evidence-based approach cannot be your only source for advancing patient safety. Anesthesia safety is a prime example. (2) Mortality during elective anesthesia has declined 10-fold in the past few decades. But this achievement was not driven by rigorous scientific evidence that certain practices reduced mortality. It wasn't attributable to any single practice, new medication, or technology. Instead, it required a broad array of changes in processes, equipment, organizational leadership, education, and teamwork—not one of which has been singled out and proven to have a clear-cut impact on mortality. Rather, safety was achieved by applying a whole host of changes that:

- Were based on an understanding of human factors principles
- Were based on dear linkage between certain processes and observed adverse events
- Were learned from the safety practices in other industries
- Made sense, considering the potential risks and benefits of the interventions. (2)

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These criteria, then -common sense, human factor-s principles, linkage between processes and adverse events, and safety practices in other Industries -should not be given short shrift in favor of evidence-based Interventions alone. In fact, it would be tragic to abandon safety initiatives like pharmacy IV admixture systems and computer-generated medication administration records simply because they're not backed by rigorous scientific evidence. And to await Irrefutable proof of effectiveness is simply not an option. We must make informed decisions based on the best available Information and common sense.

References; (1) Smith CS, Pell JP. Parachute use to prevent death and major trauma related to wavlational challenge: a systematic review of randomized control trials. BMJ 2003; 327:1459.....61. (2) leape LL, Berwick MB, Bates OW. What practices will most improve safety? Evidence-based medicine meets patient safety. JAMA 2002; 288: 501-7

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Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13)

June 5, 2013 12:05 PM Topics: Resolutions

Resolution No:109-7-13

Title: Performance Metrics and Quotas In the Practice of Pharmacy

Action: PASS

WHEREAS, a survey conducted by the Institute for Safe Medication Practices (ISMP) of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors and that 49% felt specific time measurements were a significant contributing factor; and

WHEREAS, performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment; and

WHEREAS, the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy;

THEREFORE BE IT RESOLVED that the National Association of Boards of Pharmacy (NABP) assist the state boards of pharmacy to regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians; and

BE IT FURTHER RESOLVED that NABP review and propose amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to address the regulation, restriction, or prohibition of the application of performance metrics and quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians.

(Resolution passed at the NABP 109th Annual Meeting in StLouis, MO)

II <Recognition Resolution
(Resolution 109-8-13)

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SELECTION OF STUDIES PERTAINING TO PRESCRIPTION VOLUME AND ERRORS

Pharmacist workload and pharmacy characteristics associated with the dispensing of potentially clinically important drug-drug interactions.

Comment: Well-conducted study, with a large amount of pharmacies studied (672). This study was not focused on workload specifically, but it is addressed. I would draw attention to the top of page 460, to table 5 and the accompanying paragraph, where this is addressed.

From abstract: "Factors significantly related to an increased risk of dispensing a potential DDI included pharmacist workload (odds ratio [OR] 1.03; 95% confidence interval [CI] 1.028-1.048), pharmacy staffing (OR 1.10; 95% CI: 1.09-1.11), and various technologies (eg, sophisticated telephone systems, internet receipt of orders, and refill requests) that assist with order processing, and the ability to modify DDI alert-screening sensitivity and detailed pharmacological information about DDIs."

Malone DC, Abarca J, Skrepnek GH, et al. Pharmacist workload and pharmacy characteristics associated with the dispensing of potentially clinically important drug-drug interactions. *Med Care*. 2007; 45: 456-62 Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1871111/>

National observational study of prescription dispensing accuracy and safety in 50 pharmacies.

Comment: This is probably the most heavily cited study about prescription errors. However, this study was published in 2003 and used data from 1996 Consumer Reports to conclude that pharmacists fill an average of 60 prescriptions daily. That information is clearly no longer applicable to the current work environment (the Malone et al 2007 article, above, found the studied pharmacies on average dispensed 1375 per week with an SD of 691, which would be closer to about 200 daily with an SD of about 100).

Flynn EA, Barker KN, Carnahan BJ. National observational study of prescription dispensing accuracy and safety in 50 pharmacies. *J Am Pharm Assoc*. 2003; 43: 191-200. Available at:

<http://www.japha.org/article.aspx?articleid=1036200>

Medication dispensing errors in community pharmacies: a nationwide study.

Quote: "Research is needed to investigate the impact of staffing levels and workload on pharmacy error rates. The results of this study suggest that accuracy is linked to the number of available employees for medication dispensing tasks."

Flynn EA, Dorris NT, Holman GT, Carnahan BJ, & Barker KN (2002, September). Medication dispensing errors in community pharmacies: a nationwide study. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 46, No. 16, pp. 1448-1451). SAGE Publications. Available at:

<http://faculty.zoo.com/holman/Flynn%20Dorris%20Holman%20Carnahan%20Barker%20-%20Medication%20Dispensing%20Errors%20-%20HFES%202002.pdf>

Pharmacists' dispensing accuracy in a high-volume outpatient pharmacy service: focus on risk management.

Comment: This study was conducted in 1983, so its applicability to today is somewhat questionable. Because the data was examining trends rather than amounts, and because the study was performed at a large hospital, I felt it was applicable enough to include as a small support. This study was also conducted at only 1 outpatient pharmacy, so note that there is little generalizability.

From abstract, ellipses added: "A linear relationship ($r^2 = 0.78$; p less than 0.001) existed between the number of potentially serious errors and the total number of prescriptions filled. (...) There was a trend for the number of pharmacist-hours containing at least one potentially serious dispensing error to increase as the prescription-filling rate accelerated. Outpatient pharmacies with high volumes should set a limit to the number of prescriptions filled by their pharmacists and should experiment with quality assurance systems to reduce dispensing errors and subsequent legal liabilities."

Guernsey, B. G., Ingram, N. B., Hokanson, J. A., Dautre, W. H., Bryant, S. G., Blair, C. W., & Galvan, E. (1983). Pharmacists' dispensing accuracy in a high-volume outpatient pharmacy service: focus on risk

management. *The Annals of Pharmacotherapy*, 17(10), 742-746. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/6628228>

Incidence, type and causes of dispensing errors: a review of the literature

From abstract: "High workload, interruptions, distractions and inadequate lighting were objectively shown to increase the occurrence of dispensing errors."

James, K. L., Barlow, D., McCartney, R., Hiom, S., Roberts, D., & Whittlesea, C. (2009). Incidence, type and causes of dispensing errors: a review of the literature. *International Journal of Pharmacy Practice*, 17(1), 9-30. Abstract available at: <http://www.ncbi.nlm.nih.gov/pubmed/20218026>

Challenges to the pharmacist profession from escalating pharmaceutical demand.

Quote: "The unprecedented demand for prescription drugs has challenged the pharmacist profession, and although automation and pharmacist extenders may increase dispensing efficiency, the overall demand for pharmaceutical care will remain high."

Cooksey, J. A., Knapp, K. K., Walton, S. M., & Cultice, J. M. (2002). Challenges to the pharmacist profession from escalating pharmaceutical demand. *Health Affairs*, 21(5), 182-188. Available at: <http://content.healthaffairs.org/content/21/5/182.long>

Factors influencing pharmacist performance: a review of the peer-reviewed literature.

From abstract: "Factors relating to workload and work environment were associated with performance problems, particularly in relation to errors."

Schafheutle, E. A., Seston, E. M., & Hassell, K. (2011). Factors influencing pharmacist performance: a review of the peer-reviewed literature. *Health Policy*, 102(2), 178-192. Abstract available at: <http://www.ncbi.nlm.nih.gov/pubmed/21835489>

Dispensing errors and counseling quality in 100 pharmacies.

Quote: "The dispensing error rate of more than one in five prescriptions is similar to the rate found in a similar study conducted 14 years ago, but counseling frequency has decreased significantly during the period."

Flynn, E. A., Kenneth, N. B., Berger, B. A., Lloyd, K. B., & Brackett, P. D. (2009). Dispensing errors and counseling quality in 100 pharmacies. *Journal of the American Pharmacists Association*, 49(2), 171-182. Available at: <http://japha.org/article.aspx?articleid=043574>

Workload and its impact on community pharmacists' job satisfaction and stress: a review of the literature.

From abstract: "The majority of studies suggested community pharmacists generally perceived that workload levels were increasing. Several also stated that increased workload contributed to increasing job-related stress and decreasing job satisfaction."

Lea, V. M., Corlett, S. A., & Rodgers, R. M. (2012). Workload and its impact on community pharmacists' job satisfaction and stress: a review of the literature. *International Journal of Pharmacy Practice*, 20(4), 259-271. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.2042-7174.2012.00192.x/abstract;jsessionid=5E8651E70A45F4C5305853CFA31478DB.d02t03>

Workload in community pharmacies in the UK and its impact on patient safety and pharmacists' well-being: a review of the evidence.

From abstract: "There is also some evidence to suggest a link between heavy workload and aspects of pharmacists' well-being but there is no robust evidence indicating threats to patient safety caused by their having too much work to do. More high quality research is required to examine what constitutes too much work, the impact of high workload, and associations with other work place factors."

Hassell, K., Seston, E. M., Schafheutle, E. A., Wagner, A., & Eden, M. (2011). Workload in community pharmacies in the UK and its impact on patient safety and pharmacists' well-being: a review of the evidence. *Health & social care in the community*, 19(6), 561-575. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2524.2011.00997.x/abstract>

A comment on North Carolina BOP's prescription volume rule (no longer in effect):

In "Medical Errors", edited by Michael R. Cohen in association with the American Pharmacist's association, a statement under 'Workload' in Chapter 10 Preventing Dispensing Errors read: "One state pharmacy association has served notice that pharmacists shall not dispense, and permit holders shall not allow a pharmacist to dispense, prescription drugs at such a rate per hour or per day as to pose a danger to the public health or safety; the statement mentions a threshold of 150 prescriptions per pharmacist per day." This statement was cited-in text to:

North Carolina Board of Pharmacy. Board Statement on Pharmacist Workload. March 26, 1997.

Available at: www.ncbop.org/worldoad.htm. Accessed January 3, 2006.

The Medical Errors text can be found online at

<http://books.google.com/books?id=Gpj7ZaptUDcC&printsec=frontcover#v=onepage&g&f=false>

However, the NC BOP document has been taken down, and when a member of our group contacted the NC BOP about this, they were told that no such rule is in place. According to NC BOP meeting minutes, the rule was established in 1997, and it is unclear when or why the prescription volume limit is no longer implemented. Reference to the "Pharmacist Workload Policy" can be found in these minutes available online:

[http://www.ncbop.org/about/Agendas%20and%20Minutes/Minutes03.09.pdf#search="workload"](http://www.ncbop.org/about/Agendas%20and%20Minutes/Minutes03.09.pdf#search=)

Based on this information, it is my opinion that the NC BOP may have additional insight into the issue of prescription volume and pharmacist's workloads, and they may be a valuable resource to inform this issue if asked.

Compiled by: Bridgette

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Pharmacist Workload Calculations

This is a simple calculation that illustrates the problem with the prescription volumes commonly seen today:

In an 8 hour work day, a pharmacist has 8×60 minutes "

480 minutes

Subtracting 45** minutes for both lunch and one short break leaves

435 minutes

If only 5* prescriptions are new and the pharmacist takes 5 minutes to counsel each, $5 \times 5 = 25$, leaving

410 minutes.

If a pharmacist takes only 2*** minutes to verify each prescription, $410/2 =$

205 prescriptions that can be filled in that 8 hour shift

This is at a rate of 25 prescriptions/hour.

In a study conducted in 2007, out of 672 pharmacies monitored for DD!s, those dispensing 14 prescriptions per pharmacist per hour were in the 10th percentile of errors while those dispensing 17 prescriptions per pharmacist per hour were in the 90th percentile for errors (Table 5, top of page 460). This suggests a safe filling range somewhere between 14-17.

Malone DC, Abarca J, Skrepnek GH, et al. Pharmacist workload and pharmacy characteristics associated with the dispensing of potentially clinically important drug-drug interactions. Med Care. 2007; 45:456-62 (Available at: <http://www.ncbop.org/fags/Pharmacist/PharmacistWorkload-ErrorsStudy.pdf>)

So, let's rework the calculation with an assumption of 14-17 prescriptions per hour. Breaks and counseling time do not have to be subtracted because they were included in the study which produced those figures.

8 hours * 14 prescriptions per hour verification rate =

112 prescriptions that can be verified

8 hours * 17 prescriptions per hour verification rate =

136 prescriptions verified

So, 112-136 per 8 hour shift. This is why, when pharmacists in Washington state talk about verifying upwards of 250 prescriptions per 8 hour shift, as we heard in testimony at the 4-11-13 WA BOP meeting, I get extremely concerned about practices pertaining to prescription volumes in our state.

Implementation of Oregon's OAR 855-041-1170 excerpt would not remove pharmacists' freedom to verify large volumes of prescriptions, but it would give the BOP power to prevent employers from penalizing/presiding pharmacists to fill in excess against their better judgment. (Via prohibiting "external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public"- OAR 855-041-1170.)

As stated in my presentation, I believe this is a good first step toward promoting safe practice in this state.

Notes:

*It is reasonable to conclude that a pharmacist spends at least 25 minutes per shift talking to patients in my opinion, but this is not something that has been studied or documented to my knowledge. Feel free to re-work the calculations with or without the counseling period.

**Though pharmacists often do not have a structured break, it is an assumption in law that they accrue the same amount of break time intermittently, so 45 minutes should still be accounted for over an 8 hour work shift. More information can be found here:

<http://www.lni.wa.gov/WorkplaceRights/Wages/HoursBreaks/Breaks/default.asp>

And here is a relevant article where a state (state unspecified) Supreme Court ruled that the BOP had authority to implement rules pertaining to pharmacist's break periods:

<http://www.Dharmacytimes.com/publications/issue/2007/2007-02/2007-02-6302>

***There is also little data to suggest a safe rate of minutes per verification, but the Malone DC article seems to indicate verification speed of 14-17 per hour, which is a speed of 4.2-3.5 minutes per verification. Malone DC, Abarca J, Siepnek GH, et al. Pharmacist workload and pharmacy characteristics associated with the dispensing of potentially clinically important drug-drug interactions. Med Care. 2007; 45: 456-62 (Available at: <http://www.ncbop.org/fags/Pharmacist/PharmacistWorkload-ErrorsStttdy.pdf>)

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Pharmacist Workload and Pharmacy Characteristics Associated With the Dispensing of Potentially Clinically Important Drug-Drug Interactions

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Background: Drug drug interactions (DDIs) are preventable medical errors, yet exposure to DDIs continues despite systems that are designed to prevent such exposures. The purpose of this study was to examine pharmacy characteristics that may be associated with dispensed potential DDIs.

Methods: This study combined survey data from community pharmacies in 18 metropolitan statistical areas with pharmacy claims submitted to 4 pharmacy benefit managers (PBMs) over a 3 month period from January 1, 2003 to March 31, 2003. Pharmacy characteristics of interest included prescription volume, the number of full-time equivalent pharmacists and pharmacy staff, computer software programs, and the ability to modify those programs with respect to DDI alerts, the use of technologies to assist in receiving, filling and dispensing medication orders, and prescription volume. The dependent variable in this study was the rate of dispensed medications that may interact.

Results: A total of 672 pharmacies were included in the analysis. On average (\pm SD), the respondents filled 1375 \pm 691 prescriptions per week, submitted 17,948 \pm 23,889 pharmacy claims to the participating PBMs, had 1.2 \pm 0.3 full-time equivalent pharmacists per hour open, and 545 (81%) were affiliated with a chain drug store organization. Factors significantly related to an increased risk of dispensing a potential DDI included pharmacist workload (odds ratio [OR] 1.03; 95% confidence interval [CI] 1.028-1.048), pharmacy staffing (OR 1.10; 95% CI: 1.09-1.11), and various technologies (eg, sophisticated telephone systems, internet receipt orders, and refill requests) that assist with order processing, and the ability to modify DDI alert screening sensitivity and detailed pharmacological information about DDIs.

Conclusions: This study found that there was an increase in the risk of dispensing a potential DDI with higher pharmacist and pharmacy

workload, use of specific automation, and dispensing software programs providing alerts and clinical information.

Key Words: drug drug interactions, medication safety, workload, pharmacist, medical errors

(*Med Care* 2007;45: 456-462)

The Institute of Medicine's reports on the quality of health care in the United States have highlighted the importance of reducing medical errors.¹⁻⁴ Drug-drug interactions (DDIs) are a subset of preventable errors; pharmacists are in a unique position to identify and intervene. Commonly, within community pharmacies, computer software programs assist pharmacists in identifying DDIs of potential clinical importance (hereafter termed potential DDIs). Software algorithms that identify potential interactions are often based on rules developed by proprietary companies such as First DataBank and Medi-Span; these algorithms may be modified by pharmacists or pharmacy software developers. In the normal process of entering prescription information into computer systems, alerts are generated when 2 medications in a patient's profile may interact. Previous studies have found that some pharmacists have become desensitized to the alerts and spend little time evaluating them.^{5,6} As a result of decreasing manpower,⁷ pharmacists may be required to process prescriptions at higher rates, thus reducing their ability to adequately assess potential DDIs.

Few studies have been conducted to identify pharmacy factors that might be related to higher rates of patient exposure to potential DDIs. The purpose of this study was to examine pharmacy operational characteristics and rates of dispensed potential DDIs in community pharmacies. A DDI occurs when 1 drug causes the modification of another drug, resulting in a physiological change in response to the interaction.⁸ The administration of 2 medications that may interact does not always manifest as a true DDI. Some change in physiological processes or other activity must occur for a true interaction to be present. Consequently, this study refers to pharmacy claims data indicating that 2 medications obtained by the same patient could lead to an interaction. We refer to this as a "dispensed potential DDI."

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Supported by an Agency for Healthcare Research and Quality (AHRQ) Centers for Education and Research on Therapeutics cooperative agreement (grant U18 HS10385-03 (R.L.W.)).

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ISSN: 0025-7079/07/4505-0456

METHODS

This study examines the relationship between the rate of dispensed potential DDTs and operational characteristics in community pharmacies. Pharmacy claims data submitted to 4 large pharmacy benefit managers (PBMs) were combined with survey data from community pharmacies. Participating PBMs represented approximately 120 million covered lives in the United States at the time of this study. The research was approved by the University of Arizona Human Subjects Protection Program.

Pharmacy Sample

A postal survey was used to obtain data from community pharmacies in 18 distinct metropolitan statistical areas (MSAs) or consolidated MSAs (CMSAs) in the United States (Atlanta, GA; Austin, TX; Baltimore, MD; Chicago, IL; Dallas-Ft. Worth, TX; Denver, CO; Detroit, MI; Houston, TX; Los Angeles, CA; Miami, FL; Minneapolis, MN; New York/New Jersey/Long Island; Philadelphia, PA; Phoenix, AZ; San Diego, CA; Seattle, WA; St. Louis, MO; and Washington, DC). These MSAs were selected based on the theory that pharmacies in large metropolitan areas are more likely to have a greater proportion of their prescriptions paid for by third-party payers than pharmacies located in rural areas. In addition, costs of obtaining the pharmacy sample and survey mailing expense were factors in limiting the study to these MSAs. A list of 18,596 community pharmacies with a valid National Council for Prescription Drug Programs (NCPDP) Inc. identification number in these 18 areas was obtained from American Medical Information, a proprietary medical marketing company. The NCPDP number for these community pharmacies was then sent to the participating PBMs to select pharmacies with at least 500 prescription claims submitted during June and July of 2003, which reduced the eligible sample to 9523 pharmacies. A stratified random sample of 3000 community pharmacies was selected from this list. Community pharmacies were stratified by MSA/CMSA with a minimum of 100 pharmacies selected from each area to ensure adequate representation.

Pharmacy Survey

A survey instrument specific to this study was developed, tested in a focus group, piloted and revised based upon the comments received.^{9,10} The final survey instrument contained 34 items and covered the following 4 topics: (1) workload issues, (2) use of technology in prescription processing, (3) handling of DDI alerts, and (4) pharmacists' attitudes toward computerized DDI alerts. In particular, 1 question asked if pharmacy personnel could customize the DDI alert levels and another asked whether the software provided detailed clinical information about DDIs (eg, mechanism of interaction and alternative therapies to suggest to prescribers). The results related to the pharmacists' attitudes toward DDI alerts are reported elsewhere.⁹

All correspondence to the community pharmacies was addressed to the pharmacy manager. The survey process included an announcement postcard, followed by the distribution of the questionnaire, a reminder postcard, and finally a second mailing of the questionnaire. (Each organization,

represented in the study were contacted and asked to provide a letter of support for the study. Fifteen chain organizations provided a letter of support that was sent to 555 pharmacies.

PBM Data

For survey respondents, the pharmacy NCPDP numbers were sent to the participating PBMs to determine the number of potential DDIs dispensed at that pharmacy. Twenty-five DDIs of interest based on work previously conducted by the investigators were evaluated.^{11,12} The participating PBMs ran a standard bDI algorithm developed by the research team for pharmacy claims submitted from January 1, 2003 to March 31, 2003. Results from the algorithm were provided to the research team and aggregated across the PBMs. Data were provided at the pharmacy level, including the number of dispensed potential DDIs and total prescription claim volume over the 3-month period of interest.

Data Analysis

In the data analysis we first describe the sample in terms of pharmacy personnel and operational characteristics. Data from the surveys were examined for out-of-range values and missing data. Analysis of pharmacy characteristics measured on a continuous scale was conducted using descriptive statistics. Chain pharmacies were defined as 4 or more pharmacies under the same ownership. For questions concerning the use of technology the response choices of, "Yes," "No," or "Not sure" were collapsed into 2 categories (ie, yes or no/not sure). The presence of (1) a tablet/capsule counting machine, (2) Baker cell or similar vial filling device, (3) computerized control of automated filling device, (4) a filling device that automatically attaches a label to a vial/package, and (5) a bar code scanner for medication verification was transformed from yes/no to an ordinal scale ranging from 0 (no technology) to 5 (all 5 types of technology). Additional detail on the distribution of technologies in these pharmacies is reported elsewhere.¹⁰

The next step in the analysis was to create summary measures of prescription volume, adjusted for pharmacist staffing. This was done by calculating a ratio of the reported prescriptions processed per week divided by the hours the pharmacy was open per week. The product was then divided by the total number of pharmacist hours per week. A similar ratio was created by dividing prescriptions per hour by the sum of all pharmacy staffing (pharmacists, technicians, interns, and non-technician supportive personnel) hours per week.

We then examined predictors of dispensed potential DDIs which were evaluated using a Poisson regression model, with the exposure variable being the number of prescriptions dispensed. The multivariate model adjusted for the following covariates: prescriptions per pharmacist hour; prescriptions per pharmacy staff hour; ability to customize computer generated DDI alerts; presence of software that provides detailed information about DDIs; presence of automated telephone and fax systems for new drug orders; ability to receive prescriptions via the internet; number of pharmacy terminals; affiliation to a chain pharmacy organization; and ordinal scale pertaining to the presence of technology to assist in filling prescription orders.

In addition, those pharmacies falling into the 10th and 90th percentile of dispensing potential DDIs were compared to determine if any pharmacy characteristics differed between the 2 groups. Statistical analyses were conducted using SAS 9.0 (SAS Institute; Cary, NC) and Stata 9.0 (StataCorp; College Station, TX). A type I error rate of 0.05 was chosen as the level of statistical significance.

RESULTS

A total of 755 usable surveys were returned, resulting in an overall response rate of approximately 25%. Comparisons were made between respondents and nonrespondents with respect to geographical location, ownership status (chain or nonchain), and prescription claim volume to the participating PBMs. There was no difference between respondents and nonrespondents with respect to ownership status ($P = 0.92$) or prescription claim volume ($P = 0.19$). There was a statistically significant difference between the 2 groups with respect to geographical region, with respondents more likely to be located in Denver and Phoenix. Low response rates were observed from Miami, Philadelphia, and Washington DC. To determine if response rate may have been influenced by the inclusion of a letter of support for the study from management, we examined the proportion of surveys sent with such a letter and geographical location. There was no clear relationship between those regions that had a higher proportion of pharmacies with a letter of support and response rate. For example, a letter of support was included in over 20% of sampled pharmacies located in Philadelphia and Washington, whereas 19% of pharmacies located in Denver and 36% of pharmacies located in Phoenix had such letters.

From the 15 respondents, 19 failed to report information for all the variables of interest. An additional 61 pharmacies did not have any prescription claims (and by definition no dispensed potential DDIs) from the participating PBMs during the observation period. Both of these groups were excluded. Three pharmacies had more than 1000 potential DDIs reaching their patients in the 3-month study period, which was more than twice the number of any other pharmacy. Because these pharmacies had outlier rates of DDIs, they were excluded from the primary analysis, but included in a secondary analysis to determine if the results changed.

Pharmacy personnel and operational characteristics are shown in Tables 1 and 2. On average, there were more technician hours per week (113.6 ± 71.5) than pharmacist hours (97.3 ± 37.2). In terms of pharmacist workload, the mean number of prescriptions processed per pharmacist hour was 14.1 ± 4.9 .

Most pharmacies in the sample (81.1%) were part of pharmacy chain organizations (Table 2). Most pharmacies reported that they could not customize DDI alerts, but a slight majority (56.1%) indicated that their software programs could provide detailed information about particular DDJs. Most pharmacies used some automation to assist in the repackaging and dispensing of prescription drugs, but few pharmacies had integrated filling and labeling devices. Descriptive statistics related to prescription volume, pharmacy claims, and rates of the 25 DDIs of interest are shown in

TABLE 1. Pharmacy Personnel (n 672)

Item	Mean	Std Dev	Median	Range
Pharmacist hours per week	97.3	37.2	86	36-328
Technician hours per week	113.6	71.5	100	1-507
Pharmacy intern hours per week	10.5	21.8	0	0-220
Other support personnel hours per week	28.4	54.8	0	0-508
Prescriptions per pharmacist hour	14.1	4.9	13.8	2.9-41.5
Pharmacist FTEs per hour open	1.2	0.3	1.1	0.9-5.3
Pharmacy staff FTEs per hour open	3.2	1.5	2.9	1-4.3

TABLE 2. Pharmacy Operation Characteristics (n 672)

Item	Yes(%)
Pharmacy belongs to a chain	545 (81.1)
Computer software allows customization of drug-drug interaction alerts	201 (29.9)
Computer software provides detailed information on drug-drug interactions	377 (56.1)
Pharmacy accepts new prescriptions via automated telephone system	417 (62.0)
Pharmacy accepts new prescriptions via fax	571 (85.0)
Pharmacy accepts new prescriptions via internet	230 (34.2)
Pharmacy has a patient operated telephone refill request system	536 (79.8)
Pharmacy has a patient operated internet refill request system	407 (60.6)
Pharmacy has a counter top tablet/capsule counting device	420 (62.5)
Pharmacy has a Baker cell or similar device	126 (18.7)
Pharmacy has computerized control of an automated filling device	71 (10.6)
Pharmacy has a device to automatically attach a prescription label to a vial/package	33 (4.9)
Pharmacy has a bar code scanner for medication identification/verification	364 (54.2)

Table 3. In general, the pharmacies in this study were fairly busy, filling an average of 1375 ± 691 prescriptions per week. In addition, the number of pharmacy claims submitted by respondents to the participating PBMs was almost 18,000 over a 3-month period, with a range of 64 to 179,233. In contrast, the average number of potential DDIs of interest dispensed to patients during this same period was lower (32.1 ± 56.3).

Results from the Poisson model examining factors related to dispensed potential DDIs are shown in Table 4. Pharmacist workload, overall pharmacy workload, and automated telephone systems for prescription orders were significant predictors of higher numbers of dispensed potential DDIs. The results indicate that the relative risk for dispensing a potential DDI increases by just over 3% (odds ratio [OR] 1.03; 95% confidence interval [CI] 1.028-1.034) for each additional prescription processed per pharmacist hour. The

TABLE 3. Prescription Volume, Pharmacy Claims, and Dispensed Potential Drug-Drug Interactions

Variable	Mean	Standard Deviation	Median	Range
Prescriptions filled/wk	1175	691	1251	230-5,040
Prescription claims to PBMs (over 3 mo period)	17,948	23,889	9649	64-179,233
Dispensed potential drug-drug interactions	32.1	56.3	12	1-548
Dispensed potential drug-drug interactions per pharmacy claim (%)	0.19	0.3	0.13	0.001-6.25

TABLE 4. Pharmacy Characteristics as Predictors of Potential Drug-Drug Interactions

Characteristic	Relative Risk	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Prescriptions per pharmacist hour	1.03	1.028	1.034
Prescriptions per pharmacy staff hour	1.10	1.09	1.11
Ability to customize drug-drug interaction alerts	1.23	1.19	1.26
Pharmacy software provides detailed information about drug-drug interactions	0.89	0.86	0.96
Pharmacy has automated telephone system for new drug orders	1.46	1.41	1.50
Pharmacy has fax for new drug orders	0.91	0.93	1.01
Pharmacy can receive new drug orders via intranet	0.87	0.84	0.90
Pharmacy has patient operated refill request via telephone	1.21	1.15	1.28
Pharmacy has patient operated refill request via internet	0.83	0.80	0.86
Number of computer terminals in pharmacy	0.93	0.91	0.93
Belongs to a chain pharmacy organization	1.02	0.97	1.08
Pharmacy automation of filling/dispensing	0.98	0.96	0.99
Geographic area	0.93	0.92	0.94

LR $\chi^2 = 5023$, $P < 0.001$, Pseudo $R^2 = 0.16$.

results suggest that as pharmacists become busier, they have less time to evaluate DDI warnings or to act on those warnings. Pharmacy staffing (pharmacist, pharmacy technician, and other supportive personnel) was also significantly related to dispensed potential DDIs (OR = 1.10; 95% CI 1.09-1.11). Other pharmacy characteristics related to efficient prescription order processing also were significant predictors as well, except for fax prescription order receipt and pharmacy ownership. These findings suggest that as pharmacies process more prescriptions per hour, they are more likely to dispense more potential DDIs per prescription processed. There was no significant change in the results when the 3 outlier pharmacies were included in the analysis. We also assessed the model for multicollinearity and found the variance inflation factor values did not exceed 1.85, indicating a low degree of multicollinearity.

To further investigate differences between pharmacies that had low rates of dispensed potential DDIs when compared with those with high rates, pharmacies with less than 2 ($n = 67$, 10.1%) dispensed potential DDIs per 1000 pharmacy claims and pharmacies with more than 50 ($n = 73$, 10.5%) dispensed potential DDIs per 1000 pharmacy claims were examined. Table 5 displays comparisons between pharmacies with low and high rates of dispensed potential DDIs with respect to pharmacist workload and pharmacy characteristics.

Significant differences exist with respect to the pharmacist workload between the 2 groups, with stores having higher prescriptions per pharmacist hour being associated with an increased likelihood of dispensing potential DDIs. There was no difference between low and high pharmacies with respect to the ability to customize DDI alerts ($P = 0.68$), but there was a significant difference between the 2 groups with respect to whether detailed DDI information was provided by their computer systems ($P = 0.008$). Pharmacies with higher rates of dispensed potential DDIs were more likely to have computer systems that provide detailed DDI information when compared with pharmacies with low rates of dispensed potential DDIs.

DISCUSSION

This study found that pharmacist workload, as determined by the number of prescriptions dispensed per pharmacist work hour, was significantly associated with rates of dispensed potential DDIs. Other pharmacy characteristics such as total pharmacy staffing levels and automation, were also significant predictors of dispensed potential DDIs. The findings are intuitive because pharmacies attempt to become more efficient in order processing once prescription volume exceeds existing capacity. Unfortunately, implementation of

TABLE 5. Pharmacy Volume and Pharmacist Workload Among Low and High Rates of Dispensed Potential Drug-Drug Interactions

Item	10th Percentile Pharmacies		90th Percentile Pharmacies		P
	Mean	Standard Deviation	Mean	Standard Deviation	
Prescriptions per week	1285	614	1566	648	<0.0094
Prescriptions/pharmacist hr	13.7	4.6	17.0	5.5	0.0002
Pharmacies that can customize DDT alerts	19	28.4	23	31.5	0.68
Dispensed potential drug-drug interactions per prescription claim (%)	0.12	0.04	9.99	4.68	<0.0001

automation and other pharmacy staffing may not sufficiently compensate for the increased pharmacist workload, leading to an increased risk of dispensing a potential DDI. This finding is consistent with other reports concerning workload and medication errors.¹³

Prescription volumes in community pharmacy settings have risen at phenomenal rates since the mid-1990s, from slightly over 2 billion prescriptions in 1994 to almost 3.3 billion in 2004.¹⁴ This is driven by a multitude of factors, including a greater number of unique medications, an increase in the overall population, an increasing number of elderly patients who take more medications per person, and increasing availability of prescription drug insurance. Meanwhile, the number of pharmacists in the United States has not kept pace with this trend; the number of prescriptions dispensed annually per community-based pharmacist increased from 16,500 in 1992 to 22,200 in 2000.⁵ Numerous reasons have been cited for the pharmacist shortage, including the expansion of pharmacists' practice roles, development of alternative practice settings, limited use of automation, inefficient work flow, and increased proportion of part-time pharmacists.¹⁵ Another complicating factor is that there are many more pharmacies opening annually and more pharmacies are staying open 24 hours a day. The shortage has reportedly resulted in 64% of the US population living in states where there was moderate difficulty in filling pharmacist positions.⁷ Interestingly, recent data on pharmacist workload indicate that overall there has been little change in hours worked by male and female pharmacists.¹⁶ On the other hand, pharmacists' personal prescription workload has increased from 2000 to 2004 with almost half (47%) of surveyed pharmacists reporting that their workload was high or excessively high.¹⁷ Forty-three percent of pharmacists indicated that workload had a negative impact on the opportunity to reduce potential errors. The increased workload may contribute to additional medical errors and DDIs, although the relationship between the pharmacist shortage and occurrence of medical errors is not well established.¹⁸ Although anecdotal evidence suggests increased risk of patient harm,¹⁹ no large scale studies in community pharmacies have been conducted.

The relationship between clinical pharmacy services in hospitals and medication errors, mortality, and costs has been evaluated in a series of articles by Bond and colleagues.^{20–24} These researchers found an inverse relationship between

availability of clinical pharmacy services and number of medical errors.²⁴ Most striking was that a comparison of the 10th to 90th percentile in terms of clinical pharmacist staffing found a difference in medication errors of 286%. Another study by the same authors found a statistically significant reduction in inpatient mortality among hospitals with provision of certain types of clinical pharmacist services.²¹ Other studies have also found that inclusion of clinical pharmacists in hospital settings can reduce medication errors and adverse drug events.^{25–27}

Similar to pharmacists, excessive workload is associated with higher rates of medical errors for other health professionals.^{8,29} Aiken and colleagues studied the patient-to-nurse ratio in California hospitals and found that the risk of 30-day mortality or failure to rescue (defined as deaths within 30 days of admission among patients who experienced complications) during hospitalization increased by 7% for each additional patient per nurse.⁸ Other studies have found similar relationships between nursing workloads and patient safety.²⁹ Consequently, some states now dictate minimum nurse-to-patient ratios by licensed nurse classification and by hospital unit.³⁰

Other factors may contribute to higher rates of dispensed potential DDIs. Previous research has found that pharmacists and physicians have difficulty recognizing potential DDIs.³ Widespread use of pharmacy computer systems to screen for DDIs seems to be a powerful mechanism to identify lapses in detection by pharmacists and prescribers. However, many pharmacy computer systems fail to recognize clinically important DDIs,³ and pharmacists frequently override DDI alerts.^{5,6} To our knowledge, there have been no other published reports that examine the relationship between dispensed potential DDIs and pharmacy characteristics except those related to pharmacy software systems.³⁶

The extent of harm induced by DDIs is largely unknown. Several studies have found the prevalence of clinically significant potential DDIs to be relatively low. A study using data obtained from a single PBM found that the rate of clinically important DDIs occurred at a frequency of 0.04% of all pharmacy claims dispensed.³⁷ Although the overall rate is relatively low, it is important to note that yet another study evaluating the same 25 interactions found that rates of potential DDIs varied substantially by medication pairs and by patient age.³⁸ For some interactions, such as warfarin and

nonsteroidal anti-inflammatory drugs, the prevalence was as high as 243 per 1000 persons using warfarin. In this study it was not possible to link dispensed potential DDIs to actual patient outcomes, however, researchers have found that DDIs contribute to significantly higher rates of hospitalizations.⁹⁻⁴³ In some cases, exposure to DDIs can be lethal.^{44,45}

The ability of pharmacists to multitask in busy settings has not been well studied. However, it is well known among pharmacists in community settings that interruptions are the norm. The ability to complete a task without being interrupted is limited by telephone calls from physicians or patients and questions from pharmacy support personnel or in-store customers. Frequent interruptions can have a significant effect on memory⁶; interruptions may result in loss of concentration, leading to medical errors.⁴⁷ Interruptions may also lead to a reduction in the ability of a pharmacist to appropriately follow-up on DDI alerts. This study controlled for some factors that would decrease the likelihood of interruptions and affect the rate of dispensed potential DDIs (eg, automated telephone systems for new and refill orders and internet receipt of new prescription orders). However, these factors were statistically different between pharmacies with high or low numbers of potential DDIs. Additional research is needed to investigate the impact of interruptions on the ability of pharmacists to process medication orders error-free.

There are several limitations that should be kept in mind when interpreting the results of this research. This study examined dispensed potential DDIs, but the actual patient outcomes associated with exposure to DDIs were not evaluated. Therefore, the degree of harm induced by DDIs is likely to vary according to a number of factors (eg, patient characteristics, appropriate monitoring, patient education, physician knowledge, etc). Another limitation is that this study captured potential DDIs associated with billing a third-party payer (ie, a PBM), and did not capture all prescriptions dispensed by respondents; most prescriptions (83.6%) are associated with a claim to a PBM. The relatively low response rate for this study is a concern. Thus, any findings may be subject to nonresponse error. Differences in response rates by geographical region were observed. The reason for these differences is not known, but may be due to pharmacy characteristics, appropriate monitoring, patient education, physician knowledge, etc). Another possible explanation is that pharmacies located in Eastern cities have a higher prescription volume and had less time to complete the survey. The Poisson regression models included numerous covariates of which 2 were nonsignificant: (1) chain affiliation and (2) the ability to receive new medication orders via facsimile. It is possible that the lack of significant findings may be a function of study power, leading to a type II error. The analysis included several pharmacy characteristics that are known to be related to prescription volume.¹⁰ As such, control variables were included in the Poisson model although they were not of primary interest.

CONCLUSIONS

This study found that there was an association between dispensed potential DDIs and the number of prescriptions

processed per pharmacist hour) overall pharmacy full-time equivalent staff levels, and other pharmacy characteristics that assist in the efficient dispensing of medications. This finding suggests that high workloads may lead to higher rates of exposure to potential DDIs. Future research is needed to confirm these findings and also to evaluate workflow and technological interventions that may reduce rates of dispensed potential DDIs.

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